REMARKS

At the outset, applicants thank Examiner Sheikh for her time and consideration of the present application with Dr. Moro and the undersigned on June 8, 2006. At the interview, the issues raised in the outstanding Official Action were discussed.

Claims 25-39 are pending in the present application. Independent claim 25 recites a controlled release composition, comprising a hydrophilic first matrix comprising a lipophilic phase and an amphiphilic phase, wherein the lipophilic phase and the amphiphilic phase are in a second matrix together, and said second matrix is dispersed throughout the hydrophilic first matrix. Support for claims 25-39 may be found in the specification at page 4, line 20 to page 5, line 22. Claims 1-24 have been canceled.

While claims 1-24 have been canceled and new claims 25-39 have been added, applicants do not believe that new claims 25-39 raise new issues in that the claims have recited that the lipophilic and amphiphilic matrices are dispersed in a hydrophilic matrix. As a result, applicants respectfully request that the present amendment be entered and fully considered.

In the outstanding Official Action, claims 1-14 and 20 were rejected as allegedly being obvious over AKIYAMA et al. This rejection is traversed.

As discussed and illustrated at the interview, AKIYAMA et al. fail to disclose or suggest a system wherein a hydrophilic

first matrix comprises a lipophilic phase and an amphiphilic phase, wherein the lipophilic phase and the amphiphilic phase are in a second matrix together, and the second matrix is dispersed throughout the hydrophilic first matrix.

Rather, AKIYAMA et al. teach a solid matrix composition. The composition is adapted to attach itself to the gastrointestinal mucosa. In particular, the composition is adapted to attach itself to a specific site within the gastrointestinal tract to allow the active ingredient to act directly on a living body (page 2, lines 44-45). In order to impart this property, a viscogenic agent is required (page 3, lines 36-38). AKIYAMA et al. teach that the composition may comprise matrices of A, B, and C. While a viscogenic agent may be dispersed throughout each matrix, the matrix themselves are not taught as being dispersed within another matrix. (column 9, lines 50-60). This provides a stratified reservoir system. Thus, although AKIYAMA et al. refer to a "matrix", it is a composition distinct from the composition recited in the claims.

Thus, in view of the above, applicants respectfully submit that AKIYAMA et al. fail to disclose the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, applicants believe that the present application is in condition for allowance at the time of the next

Application No. 10/009,532 Docket No. 2551-1001

Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

Philip A. DuBois, Reg. No. 50,696

745 South 23rd Street Arlington, VA 22202 Telephone (703) 521-2297 Telefax (703) 685-0573

(703) 979-4709

PD/lk

. . . .